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Chiron Corporation
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P.O. Box 8097
Emeryville, CA 94662-8097

EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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02/21/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/758,575

Applicant(s)

KAUFMANN ET AL.

Examiner

Alana M. Harris, Ph.D.

Art Unit

1643

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-11 and 36-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1 and 6-11 is/are allowed.
- 6) ☒ Claim(s) 5 and 36-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments and Amendments

1. Claims 1, 5-11 and 36-49 are pending.
Claims 46-48 have been amended.
Claim 49 has been added.
Claims 1, 5-11 and 36-49 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

4. The **NEW MATTER REJECTION** of claim 47 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth on page 3, section 6 of the Action mailed August 28, 2007 is withdrawn in light of the amendment to the claim submitted November 30, 2007.
5. The rejection of claims 5 and 36-48 under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement is withdrawn.

Maintained and New Grounds of Rejection

Claim Rejections - 35 USC § 112

6. The rejection of claims 47 and 48 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is made and maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **THIS IS A NEW MATTER REJECTION.**

Applicants assert their independent claims 5, 36 and 39 provide some variability in nucleotide sequence, SEQ ID NO: 1, see page 7 of Remarks. Moreover, they assert claim 48 provides further identifying characteristics of the claimed polynucleotide, reciting a portion of the polynucleotide which encodes SEQ ID NO: 2. Claim 47 has the same circumstance. Applicants aver the variability in SEQ ID NO: 1 set forth in claims 5, 36 and 39 does not occur at the region corresponding to the nucleotide fragment cited in claim 48. Applicants reiterate the nucleotide fragments of SEQ ID NO: 1 represent a region of *SEQ ID NO: 1173* (the Examiner assumes Applicants mean SEQ ID NO: 1). These arguments and points of view have been carefully considered, but found unpersuasive.

These arguments do not obviate the instant rejection. Applicants are reminded claims 47 and 48 depend from three independent claims, which read on the isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide; a polynucleotide at least 95% identical to a polynucleotide; and a polynucleotide encoding

a polypeptide at least 95% identical to SEQ ID NO: 2 wherein the nucleic acid molecule comprises nucleotides 365-1173 of SEQ ID NO: 1. The Examiner does not note support for the fragments of SEQ ID NO: 1 encoding a polypeptide (amino acids 1 to 273; amino acids 2 to 273; nor 26 to 273 of SEQ ID NO: 2); the fragments of SEQ ID NO: 1 encoding a polypeptide at least 95% identical to SEQ ID NO: 2. The fragment listed in claims 47 and 48 are recited in the specification, page 22 and page 23, respectively. However, it remains the context of these recitations do not overlap with the claimed invention. In essence, these passages within the specification do not support the breadth of the claims. Applicants should delete the new matter or point out support for claims 47 and 48.

7. The rejection of claims 5 and 36-49 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained and made. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants' arguments note *Ex parte Sun* and attempt to set forth an analogy between the said case and their instant application, see page 10 of the Remarks. Applicants assert Example 14 of the Guidelines parallels Applicants' claims, wherein a genus of molecules are presented, which include variants but have specified activity and identity to the wild-type protein, see pages 10 and 11 of the Remarks. These points

of view, arguments, as well as the Guidelines have been carefully reviewed by the Examiner, but found unpersuasive.

The Guidelines Applicants' reference, particularly Example 14 does set forth a situation wherein a protein with a known sequence has variants with defined sequence identity and defined function. However, Applicants failed to further delineate the protein in the Example has a catalytic domain, which is defined, therefore one of ordinary skill in the art would know which residues can and cannot be altered or deleted in order to retain or lose activity. Applicants' instant claims do not afford such information. There is no information that addresses for example, which nucleic acid variants of SEQ ID NO: 1 and which amino acids within 26 to 273 of SEQ ID NO: 2 must retain the 95% sequence homology to SEQ ID NO: 2 in order to have applicability in assessing overexpression in metastatic human breast cancer cells. Moreover, overexpression in metastatic human breast cancer cells as compared to low or non-metastatic human breast cells is a characteristic and not function *per se*. A function is a kind of action, activity or factor dependent upon other factors. Overexpression of a polypeptide in one set of cells compared with another set of cells is not a function, but rather a characterization, distinguishing features or qualities.

Applicants' specification cites SEQ ID NO: 1 also known as human Out at First (hsOAF), see Figure 1; and page 11. And while Applicants seem to be in possession of hsOAF protein defined as SEQ ID NO: 2 and encoded by the nucleic acid identified as SEQ ID NO: 1. Applicants have not provided sufficient evidence that they were in possession of the infinite number of molecules with 95%-98% sequence homology and

comprise at least one amino acid substitution that are considered variants of SEQ ID NO: 2, those molecules less than 100% sequence identical to SEQ ID NO: 2. The same applies for polynucleotides of less than 100% sequence identity to SEQ ID NO: 1.

For the reasons of record and those cited herein there still continues to be insufficient to support the generic claims as provided by the Interim Written Description Guidelines published in the June 15, 1998 Federal Register at Volume 63, Number 114, pages 32639-32645.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 47-49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 47 and 48 are indefinite because it is clear and acknowledged by Applicants that nucleotide fragment 365-1173 and nucleotide fragment 446-1173 of SEQ ID NO: 1 do not encode amino acids 1 to 273; amino acids 2 to 273; nor 26 to 273 of SEQ ID NO: 2. However, their dependency upon claims 5, 36 and 39 suggest so. Applicants are requested to clarify.

b. Claim 49 is indefinite because it implies conservative amino acid substitutions are made within the isolated nucleic acid molecule. This art known not to be possible. Applicants are requested to clarify.

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571)272-0831. The Examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm, with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER


Alana M. Harris, Ph.D.

14 February 2008